



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 25, 2004

Mr. Roger A. Glade, President
Fay's Foods, Inc.
10650 Burbank Boulevard
North Hollywood, CA 91601

W/L 30-04

Dear Mr. Glade:

The Food and Drug Administration conducted an inspection of your facility located at 10650 Burbank Boulevard, North Hollywood, CA 91601 on 1/12/2004 through 1/16/2004. At the conclusion of the inspection you were issued a Form FDA-483 (copy attached) which listed a number of gross insanitary conditions present in your firm at the time of that inspection. These conditions cause the products processed in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act) in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

The following is a list of the insanitary conditions observed by our investigator during the inspection, referenced to current Good Manufacturing Practice regulations for human foods, Title 21, Code of Federal Regulations (21 CFR).

1. Failure to manufacture, package, and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination. (21 CFR 110.80(b)(2))

Specifically,

- a) Six white square buckets of ready-to-eat tuna salad were observed covered with mildew stains. This black mildew growth was observed on the outside and inside seams and edges of the lids that came in contact with ready-to-eat tuna salad. The containers of tuna salad were taken to the processing room for making tuna salad croissant sandwiches.

- b) During tuna salad croissant sandwich processing, a female employee was observed scooping out tuna salad from a white square bucket that was covered with black mildew stain on its outside bottom. It was resting on the surface of assembly line for ready-to-eat sandwiches.
 - c) The working surfaces in the processing room were observed being wiped with towels that had been soaked in a bucket of water in the sink; no sanitizing solution such as chlorine was detected in the water.
 - d) During tuna salad croissant sandwich processing, two female employees were utilizing cloth square mats covered with mildew and dark stains under their cutting boards used to make ready-to-eat sandwiches.
 - e) Containers of prepared salads were observed directly sitting on carrying carts covered with black grime residue. These containers were placed directly on the two processing line tables during the sandwich assembly.
 - f) A two level plastic cart placed next to the assembly line was observed cracked and broken, covered with dark stains and deep grooves and was storing pita bread on the top level. The second level of the cart was utilized for storage of containers of sliced cheese; the surface underneath the top level was observed covered with built-up stains of yellowish dark colors.
 - g) Cleaning towels, used for wiping food contact surfaces, were observed stored on an unsanitary cart covered with a build-up of dark grime accumulation.
 - h) The plastic strip curtain covering the entrance to the firm's processing area was cracked, stained with a built-up accumulation, and contained food stickers. Containers of raw material and finished products were observed coming in direct contact with these soiled strips.
 - i) Finished ready-to-eat sandwiches, salads and loaves of bread were observed stored on the entrance aisle of the processing room across from two restrooms that open directly to the processing area.
2. Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials. (21 CFR 110.35(a))

Specifically,

- a) The firm does not utilize any type of cleaning solution to clean processing surfaces between production runs. The firm is relying on wiping surfaces with a sanitizing solution once every day.
- b) During processing on 1/12/04, one bucket full of water with no sanitizer was utilized as

a sanitizing station for approximately twenty processing employees to rinse their towels and wipe their surface area so reduce cross contamination in between production runs.

- c) The firm's cleaning/sanitizing station for equipment and utensils is not adequate.
3. Failure to have smoothly bonded or well maintained seams on food contact surfaces to minimize accumulation of food particles, dirt, and organic matter and the opportunity for growth of microorganisms. (21 CFR 110.40(b))

Specifically, cutting boards utilized for processing ready-to-eat sandwiches, cut vegetables and fruit were observed stained and covered with deep cuts and grooves.

4. Failure to adequately wash and clean raw materials as necessary to remove soil or other contamination. (21 CFR 110.80(a) (1))

Specifically, the firm does not wash the melons such as honey dew and cantaloupe prior to processing. On 1/12/04 during the processing in the kitchen, a male employee was observed taking honey dew melons right out of their its original shipping box stored on top of the processing table, peeling them with an un-sanitized knife that was stored in a plastic milk crate, cutting them in half on a cutting board covered with deep grooves and dark bluish stains, and storing them in plastic containers covered with yellowish sticky residue and mildew on the bottom.

5. Failure to sanitize and thoroughly dry, prior to use, food-contact surfaces which have been wet cleaned. (21 CFR 110.35(d) (1))

Specifically, several stacks of washed ready- for- use stained plastic buckets and containers were observed covered with mildew around the seams and handles and containing a slimy sticky yellowish film in the inside. The containers were wet, with water remains accumulating in them.

6. Toilet doors open into areas where food is exposed to airborne contamination, and there are no alternative means taken to prevent such contamination. (21 CFR 110.37(d) (4))

Specifically, the firm has two employee restrooms located in the firm's processing room near the entrance opening directly into the processing area.

7. Failure to provide hand washing and hand sanitizing facilities at each location in the plant where needed. (21 CFR 110.37(e) (1))

Specifically, the firm does not provide a hand cleaning /sanitizing station for employee use.

8. Failure to take effective measures to protect against the inclusion of metal and extraneous material in food. (21 CFR 110.80(b) (8))

Specifically, the firm does not utilize any detecting device for protecting its ready-to-eat salads and sandwiches against any physical hazard such as glass or metal inclusions.

9. The plant is not constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and kept in good repair. (21 CFR 110.20(b)(4))

Specifically,

- a) The processing room's floor, walls and ceiling were not kept clean and were covered with build-up. The processing room is set-up so that the raw and finished products are stored directly against the wall.
 - b) The floor of processing room was covered with mats covered with trash and food particles. No wet cleaning is performed at the end of every day operation (the floor is solely swept), and the firm performs a once-a-month wet-dry cleaning operation.
10. Responsibility for assuring compliance with current good manufacturing practice relating to personnel has not been assigned to competent supervisory personnel. (21 CFR 110.10(d))

Specifically, the supervisor in charge of processing and cleaning was not knowledgeable in Good Manufacturing Practices to recognize and correct the unsanitary situations observed during the inspection.

11. Effective measures are not being taken to protect against the contamination of food on the premises by pests. (21 CFR 110.35(c))

Specifically,

- a) The firm does not allow adequate spacing between equipment, raw goods, finished goods, and facility walls to accommodate cleaning and control pest harborage.
 - b) The facility was observed kept unclean and covered with food and non-food particles within its storage areas.
 - c) The firm does not have traps set up within processing and storage areas to control pests.
12. Failure to store raw materials in a manner that protects against contamination and minimizes deterioration. (21 CFR 110.80(a) (1))

Specifically, damaged and opened boxes of raw materials were observed in the firm's freezer.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject your firm to legal action. It is your responsibility to assure that all

Letter to Mr. Roger A. Glade, Fay's Foods, Inc.

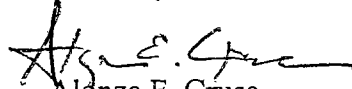
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of your products are in compliance with the Act. You should take prompt action to correct the violations observed during FDA's most recent inspection. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each such item will be corrected and documented state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Director, Compliance Branch, 19701 Fairchild Ave, Irvine, California 92612-2506. If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-608-4428.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse", written over a horizontal line.

Alonza E. Cruse
District Director

Cc: Department of Health Services
Chief, Food and Drug Branch
P.O. Box 997413, MS-7602
Sacramento, CA 95899-7413